REMARKS

Reconsideration of the application is respectfully requested.

Claims 1-15 and 21-35 are in the application.

In the Official Action, the Examiner rejected claims 1-15 and 21-35 as being allegedly unpatentable over Bitdinger et al. (U.S. Patent No. 5,478,316). This rejection was previously applied and Applicant addressed this rejection in a response filed on June 27, 2008. At p. 2 of the present Office Action, the Examiner responded to Applicant's arguments of June 27, 2008 and stated:

> Applicants argue that the amended claim language of an extended position "wherein a distal end of said shield extends beyond a distal end of said holder and said needle cannula is enclosed by said shield" is not shown in the prior art of record (Bitdinger). Examiner is considering the retracted position to be shown in figure 6-7, and the extended position to be shown in figures 5 or 8. Note that in figure 5 for example the distal end of the shield (where F arrow point) is extending beyond the distal end of the holder (12 or 12B) and the needle cannula 38 is enclosed by shield (28). The elements disclosed in Bitdinger are fully capable of satisfying all structural, functional, spatial, and operational limitations in the amended claims, as currently written, and the rejection is made.

The Examiner's assertions are respectfully traversed.

Bitdinger et al. is directed to an automatic self-injection device. The device includes a sleeve 28 formed to enclose needle 38. Fig. 3 shows the device prior to use with the sleeve 28 covering the needle 38. (See, col. 3, ll. 33-44). With reference to Fig. 5, the sleeve 28 covers the needle 38 ***prior to use***. The sleeve 28 is pressed against a patient's skin to initiate use. (See, col.

5, ll. 51-59). As shown in Figs. 6-8, ***after use***, the sleeve 28 is driven back to a shielding position, as shown in Fig. 8. (See, col. 6, ll. 22-28).

Claims 1, 12, 21 and 31 are the pending independent claims of the application. As stated in each of these independent claims, the shield is ***initially*** in the retracted position. Further, as defined in each of these independent claims, the retracted position is defined as the position where the "needle cannula is exposed". Further, in each of the independent claims, the shield is caused to move from the retracted position to the extended position. As set forth in each of the independent claims, the extended position is a position where a distal end of the shield extends beyond the distal end of the holder and the needle cannula is enclosed by the shield. Thus, in taking a complete reading of each of the independent claims, the shield is:

1. in an initial position where the needle cannula is exposed; and,

2. caused to move to an extended position where the needle cannula is enclosed by the shield.

As set forth above, the sleeve 28 in Bitdinger et al. is ***initially*** in a position covering the needle 38. In sequence, the covering position shown in Fig. 5 of Bitdinger et al. occurs before the retracted position shown in Fig. 6. Thus, the sleeve 28 of Bitdinger et al. is ***not*** initially in a retracted position. Rather, it is initially in an extended position.

Furthermore, a spring causes the sleeve 28 to move from the position shown in Fig. 6 of Bitdinger et al. to the position shown in Fig. 8. (See, col. 6, ll. 22-28). The syringe in Bitdinger

et al. does not move from the position shown in Fig. 6 to Fig. 8. As set forth in each of the independent claims, axial movement of the barrel or syringe relative to the holder causes movement of the shield from the retracted to the extended position. If the retracted position is taken to be shown in Fig. 6 of Bitdinger et al., ***no*** axial movement of the syringe is relied upon to cause movement of the sleeve 28 from the position shown in Fig. 6 to the position shown in Fig. 8. Rather, the sleeve 28 is driven by the sleeve spring. It is respectfully submitted that claims 1, 12, 21 and 31, along with dependent claims 2-11, 13-15, 22-30 and 32-35, are patentable over Bitdinger et al.

In the Official Action, the Examiner rejected claims 1, 12, 21 and 31 under 35 U.S.C. §112, second paragraph, as being allegedly incomplete for omitting essential structural cooperative relationships of elements. The Examiner specifically indicated that "applicant's spring is biased between the shield (59) then collar element (66) then barrel flange 24, then holder (40). Examiner is not able to see where the spring directly biases the shield (59) with the holder (40)."

The basis of this rejection is unclear. In Applicant's last response, Applicant responded to this same rejection. As stated therein, there is no requirement in the claims that the "spring directly biases the shield". The Examiner's statement that the "Examiner is not able to see where the spring directly biases the shield (59) with the holder (40)" is unclear.

Moreover, as set forth at MPEP §2172.01, essential matter is defined by the specification. MPEP §2164.08(c) indicates that,

> [A]n enablement rejection based on the grounds that a disclosed critical limitation is missing from a claim should be made only when the language of the specification makes it clear that the limitation is critical for the invention to function as intended. ***Broad language in the disclosure, including the abstract, omitting an allegedly critical feature, tends to rebut the argument of criticality.***

(Emphasis added).

Support for the spring being within the holder, as set forth in claims 1, 12, 21 and 31, is provided in the subject application. Further, with reference to para. [0027] in the specification as originally filed (para. [0030] in the application as published), it is stated that:

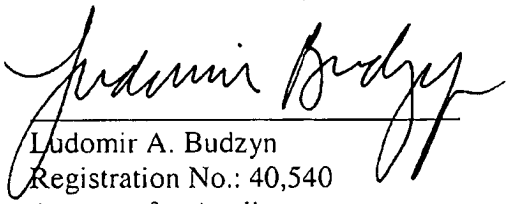
> Direct engagement of the end fitting 32 or syringe flange 24 and shield, as provided in the preferred embodiment, is not necessary in such an arrangement. The operation of the device can be effected whether the shield, spring, and fitting and syringe barrel are ***directly or indirectly engaged***, so long as axial movement of the syringe barrel causes axial movement of the shield. As discussed below, the use of an end fitting is preferred, but optional.

Thus, it is clear from the specification that the spring may be "directly or indirectly engaged". The Examiner stated in the rejection that the "Examiner is not able to see where the spring directly biases the shield (59) with the holder (40)." The claims do not state such a limitation – there is no requirement in the claims that the spring directly biases the shield. Claims 1, 12, 21 and 31 require that the spring be "within said holder". It is clear from the specification and the drawings of the subject application that support for the spring being within the holder is present. In addition, as set forth in the quote above, direct or indirect engagement of the spring is disclosed. There is no requirement for direct biasing, as suggested by the Examiner. It is

respectfully submitted that claims 1, 12, 21 and 31 are in accord with 35 U.S.C. §112.

Favorable action is earnestly solicited. If there are any questions or if additional information is required, the Examiner is respectfully requested to contact Applicants' attorney at the number listed below.

Respectfully submitted,



Ludomir A. Budzyn
Registration No.: 40,540
Attorney for Applicants

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(973) 331-1700